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DERIVATIVE SPECTROPHOTOMETRIC ESTIMATION OF ELOBIXIBAT IN PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

The first derivative Spectrophotometric method in Ethanol have been developed for the determination of Elobixibat in bulk drug and its pharmaceutical formulations. Elobixibat exhibits absorption maxima at 230 nm. In the first derivative spectra of Elobixibat, the amplitude of positive maxima was measured at 230 nm. Linearity in the concentration range was found to be 1-10 µg/ml. The results of analysis have been validated statistically and also by recovery studies. The method were found to be simple economical accurate and reproducible and can be adopted in routine analysis of Elobixibat in bulk drug and Pharmaceutical dosage form.

KEYWORDS: Elobixibat, first derivative spectrophotometry, IBAT etc.

INTRODUCTION

Elobixibat is 2-[(2R)-2-(2-{[3,3-dibutyl-7-(methylsulfanyl)-1,1-dioxo-5-phenyl-2,3,4,5-tetrahydro-1lambda6,5-benzothiazepin-8-yl]oxy}acetamido)-2-phenylacetamido]acetic acid. Elobixibat is an ileal bile acid transporter (IBAT) inhibitor used to treat chronic constipation. Its mechanism of action involves blocking the reabsorption of bile acids in the ileum, which increases the amount of bile acids in the colon, leading to increased fluid and electrolyte secretion and enhanced gastrointestinal motility. No derivative spectrophotometric method has been reported for routine quality control analysis of Elobixibat. The present investigation illustrates simple, sensitive and accurate derivative spectrophotometric method for the analysis of Elobixibat in bulk drug and Pharmaceutical formulations.

EXPERIMENTAL SECTION

MATERIAL AND METHODS

Materials and Reagents

Elobixibat generous gift sample from Dr. Reddy's Lab (Hyderabad, India). A commercial Bixibat (Dr. Reddy's Lab) tablet containing 5 mg were purchased from a local market and used within their shelf-life period. All chemicals used were of analytical reagent grade.

Instrumentation

Shimadzu-1800 UV-Visible double beam spectrophotometer with 1cm matched quartz cell was used to measure absorbance of the resulting solution.

Preparation of stock solution and sample solution

A typical high-concentration stock solution is prepared first and then diluted as needed. A common concentration is 1 mg/mL (1000 µg/mL) or 50 mg/50 mL. Accurately weigh about 5**0 mg** of pure Elobixibat standard using an analytical balance. Transfer the weighed powder into a **50 mL volumetric flask**. Add a small amount (e.g., 25 mL) of Ethanol (or other chosen solvent) to the flask. Swirl and/or sonicate the mixture for about 15-30 minutes to ensure complete dissolution of the drug. Once dissolved, dilute to the mark with methanol and mix well to obtain a stock solution with a concentration of **1000 µg/mL** (1 mg/mL). This solution can be stored as a stock.

For spectrophotometry, lower concentrations are used, typically within a linear range (Beer's Law limits, e.g., 1-10 µg/mL).

Preparation of standard calibration curve for Ethanol
The standard calibration curves of Elobixibat was plotted to check the linearity between concentration and absorbance i.e. up to which concentration Beer's law is followed. This is useful to ascertain concentration range of the drug to utilized for difference spectrophotometric analysis. Standard solution of Elobixibat were transferred into ten 10ml volumetric flasks and diluted with Ethanol solution in order to get final concentration 1 to 10 ug/ml of Elobixibat respectively. Each solution is scanned between 200nm to 400nm using spectrum mode of instrument to determine λmax of Elobixibat in Ethanol was found at 230nm. The linearity data of Elobixibat is given in the below table. The linear regression equation for Elobixbat in Ethanol was found to be Y=o.o33x+0.072, and r^2=0.9997.

Elobixibat tablets containing 5 mg EBX were analysed by the proposed method. For the analysis of pharmaceutical formulations, Ten tablets EBX were weighed and powdered Seperately. A quantity equivalent to labeled amount was weighed and transferred into conical flask and dissolved in Ethanol and sonicate for about 15 minutes, then it was filtered through whatman filter paper no.41 into a calibrated 10ml volumetric flask. Filter paper was rinsed twice with 1ml each of Ethanol and was made upto 10ml with Ethanol .Appropriate aliquots was then taken in such a way that the final concentration in 10ml volumetric flask were within the range used for testing the drug.

RESULTS AND DISCUSSION

The optical characteristics such as Beers' law limit, molar extinction coefficient, LOD, LOQ, percent relative standard deviation and percentage range of error at 95% confident limit of all the methods were incorporated

Method Validation
The method was validated as per **ICH Q2(R1) guidelines.**

Linearity and Range
1 to 10µg/mL.

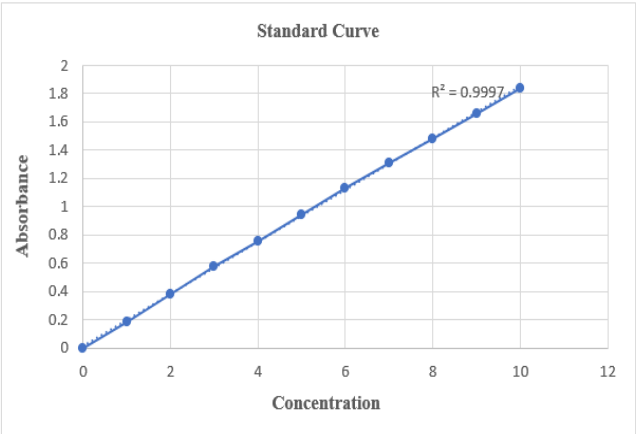
Precision
Intra-day and inter-day precision of the assay samples containing Elobixibat (10, 15, and 200 µg/ml) were analyzed four times in the same day (intraday), and for three consecutive days by different analysts. Precision was calculated and given in terms of mean % ± S.

Accuracy
It was found out by recovery study using standard addition method. Known amounts of standard Elobixibat was added to pre-analyzed samples at a level from 80% to 120% and then subjected to the proposed method. Results of recovery studies are shown.

Sensitivity
LOD and LOQ decide about the sensitivity of the method. LOD is the lowest detectable concentration of the analyte by the method while LOQ is the minimum quantifiable concentration. LOD and LOQ were calculated by the equations as given in ICH guidelines.
LOD=3.3σ/s **LOQ=10σ/s**

LOD and LOQ for Elobixibat were found to be 0.057 and 0.1748 µg/ml, respectively, these data show high sensitivity of the method.

Ruggedness of the proposed methods was studied with the help of two analysts. Robustness of the methods was studied in two different laboratories using UV- visible spectrophotometer. The results did not show any statistical difference between operators and environmental conditions, suggesting that methods developed were rugged and robust. The results from validation studies.



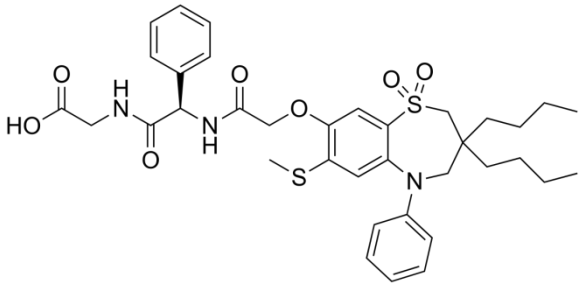
Elobixibat standard curve in Ethanol.

Table no. 1: Absorbance table of Elobixibat standard curve in Ethanol.

Sr. No.	Concentration (µg/mL)	Absorbance at 230 nm
1.	0	0
2.	1	0.187
3.	2	0.382
4.	3	0.574
5.	4	0.756
6.	5	0.943
7.	6	1.13
8.	7	1.306
9.	8	1.484
10.	9	1.662
11.	10	1.835

Table 2: Optical characteristics, precision and accuracy of Elobixibat (EBX)

Sr.No.	Parameter	BX
1	Absorption Maxima (nm)	230 nm
2	Linearity range (µg/ml)	1-10 µg/mL
3	Molar Absorptivity (L/mol/cm)	$1.33x10^{-1}$
4	Correlation Coefficient (r)	0.9997
5	Slope (B)	0.033
6	Intercept (A)	0.072



Structure of Elobixibat

CONCLUSION

The proposed method was found to be simple, precise, accurate and rapid for determination of Elobixibat from pure and pharmaceutical formulations. All the proposed methods produce comparable results and can be used for precise and accurate analysis of EBX in its pure and in Tablet dosage forms. Interference studies revealed that the common excipients and other additives usually present in the dosage form did not interfere in the method. The values of standard deviations were satisfactory and percentage recovery was close to 100% indicating the reproducibility and accuracy of the methods can be employed as a quality control tool for the analysis of Elobixibat in dosage forms.

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